

WHAT IS CLAIMED IS:

1. A composition for administering a cyclosporin compound, the composition comprising:
 - (a) a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, particles of a size of less than about 100 nm, said dispersible concentrate comprising:
 - (i) at least one surfactant; and
 - (ii) a hydrophilic solvent characterized by being a lower alkyl ester of hydroxyalkanoic acid or an N-alkyl pyrrolidone; and
 - (b) a pharmaceutically effective amount of the cyclosporin compound.
2. The composition of claim 1, wherein said hydrophilic solvent includes a lower alkyl hydroxy alkanoic acid ester.
3. The composition of claim 2, wherein said lower alkyl hydroxy alkanoic acid ester includes ethyl lactate.
4. The composition of claim 1, wherein said hydrophilic solvent includes a lower alkyl N-alkyl pyrrolidone.
5. The composition of claim 4, wherein said lower alkyl N-alkyl pyrrolidone includes N-methyl pyrrolidone.
6. The composition of claim 1, wherein said hydrophilic solvent includes a combination of a lower alkyl ester of N-alkyl pyrrolidone and a lower alkyl hydroxy alkanoic acid ester.
7. The composition of claim 1, wherein said at least one surfactant is a combination of at least two surfactants, at least one surfactant of said combination being a high HLB (hydrophilic/lipophilic balance) surfactant having an HLB of at least about 8, and at least one surfactant of said combination being a low HLB surfactant having an HLB of less than about 5.

8. The composition of claim 7, wherein said combination is a combination of polyoxyethylene(20)sorbitan monolaurate and sorbitan monooleate.

9. The composition of claim 7, further comprising:

(c) an ethoxylated fat.

10. The composition of claim 9, wherein said ethoxylated fat is selected from the group consisting of polyethyleneglycol-hydrogenated castor oils.

11. The composition of claim 10, wherein said ethoxylated fat is selected from the group consisting of Cremophor™ EL, Cremophor™ RH 40 and Cremophor™ RH 60.

12. The composition of claim 9, further comprising:

(d) a phospholipid.

13. The composition of claim 12, wherein said phospholipid is selected from the group consisting of egg phospholipid and soy phospholipid.

14. The composition of claim 12, further comprising:

(e) a fatty acid ester.

15. The composition of claim 14, wherein said fatty acid ester is a solid fat at room temperature.

16. The composition of claim 15, wherein said fatty acid ester is tricaprin.

17. The composition of claim 1, wherein said particle size is less than about 60 nm.

18. The composition of claim 17, wherein said particle size is in a range of from about 5 nm to about 50 nm.

19. The composition of claim 1, wherein the cyclosporin compound is Ciclosporin.

20. A composition for administering a cyclosporin compound, the composition comprising a pharmaceutically effective amount of the composition of claim 1, and an aqueous solution as a diluent for said pharmaceutically effective amount of the composition of claim 1.

21. A composition for administering a cyclosporin compound, the composition comprising a lyophilized composition, said lyophilized composition being formed from a pharmaceutically effective amount of the composition of claim 1 and an aqueous solution as a diluent for said pharmaceutically effective amount of the composition of claim 1 to form a diluted solution, said diluted solution being lyophilized to form said lyophilized composition.

22. A method for administering a cyclosporin compound to a subject, the method comprising the step of administering a pharmaceutically effective amount of the composition of claim 1 to the subject.

23. The method of claim 22, wherein said pharmaceutically effective amount of the composition of claim 1 is administered to the subject through oral administration.

24. The method of claim 23, wherein said pharmaceutically effective amount of the composition of claim 1 is administered as a dispersion with an aqueous solution as a diluent.

25. A method for determining storage stability of a formulation containing a cyclosporin compound, the method comprising the step of analyzing the composition of claim 1 for particle size, such that if said particle size is less than about 100 nm, the formulation is determined to be stable.

26. A composition for administering a cyclosporin compound, the composition comprising:

- (a) a dispersible concentrate characterized by being capable of forming, upon contact with an aqueous solution, particles of a size of less than about 100 nm, said dispersible concentrate comprising:

- (i) an ethoxylated fat; and
 - (ii) a hydrophilic solvent characterized by being a lower alkyl ester of hydroxyalkanoic acid or an N-alkyl pyrrolidone; and
- (b) a pharmaceutically effective amount of the cyclosporin compound.

27. The composition of claim 26, wherein said ethoxylated fat is selected from the group consisting of polyethyleneglycol-hydrogenated castor oils.

28. The composition of claim 27, wherein said ethoxylated fat is selected from the group consisting of Cremophor™ EL, Cremophor™ RH 40 and Cremophor™ RH 60.

29. The composition of claim 26, wherein said hydrophilic solvent includes a lower alkyl hydroxy alkanolic acid ester.

30. The composition of claim 29, wherein said lower alkyl hydroxy alkanolic acid ester includes ethyl lactate.

31. The composition of claim 26, wherein said hydrophilic solvent includes a lower alkyl N-alkyl pyrrolidone.

32. The composition of claim 31, wherein said lower alkyl N-alkyl pyrrolidone includes N-methyl pyrrolidone.

33. The composition of claim 26, wherein said hydrophilic solvent includes a combination of a lower alkyl ester of N-alkyl pyrrolidone and a lower alkyl hydroxy alkanolic acid ester.